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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,525	08/29/2005	Barry Sinclair Brewster	ISA-032.01	2520
63767	7590	04/12/2010	EXAMINER	
FOLEY HOAG, LLP			SIEFKE, SAMUEL P	
PATENT GROUP (w/ISA)				
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BOSTON, MA 02210-2600			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,525

Applicant(s)

BREWSTER ET AL.

Examiner

SAM P. SIEFKE

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 27-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandler (USPN 5,468,648).

Chandler discloses an assay device according to the present invention can comprise: a first opposable component including at least one chromatographic medium (nitrocellulose transparent medium) having a specific binding partner to the first analyte and a specific binding partner to the second analyte immobilized thereto in separate, discrete, non-overlapping zones; and (2) a second opposable component including an absorber. The first and second opposable components are configured such that bringing the first and second opposable components into opposition causes the absorber to come into operable contact with at least one chromatographic medium so that the zone containing the specific binding partner to the first analyte is functionally divided from the zone containing the specific binding partner to the second analyte so that both analytes can be detected (abstract). The chromatographic medium is composed of a material or materials suitable as a medium for thin layer chromatography of analyte and analyte-antibody conjugates, such as nitrocellulose, nylon, rayon,

cellulose, paper, or silica. Preferably, the chromatographic medium is nitrocellulose. The chromatographic medium can be pretreated or modified as needed. The chromatographic medium is translucent, so that colored bands appearing on it can be viewed from either side (col. 13, lines 45-68). Regarding claim 1, these claims include intended use limitations (i.e. operable to, printing the colored line, using an ink, when dry operation, wet operation), which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited intended use limitations are accorded no patentable weight to an apparatus. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114). The first opposable component 302 further includes a printed limit line 334 and a second

conductor (Ahlstrom 1281) 336. The limit line 334 is located between the detection zone 332 and the second conductor 336. The first and second chromatographic medium 322 and 328 and the first and second conductors 326 and 336 are backed by a polycarbonate test strip backing (Lexan) 338.

Response to Arguments

Applicant's arguments filed 12/28/09 have been fully considered but they are not persuasive. Applicant argues, "Chandler describes a device comprising a first opposable component including at least one chromatographic medium, and a second opposable component including an absorber. Chandler does not disclose or suggest a device with a nitrocellulose strip having an upper surface, a lower surface, and a line printed or deposited on the lower surface, as required by claim 1." The claim states an upper surface, a lower surface, and a line printed on the lower surface. The Examiner states that the upper surface in figure 4 of Chandler would be the surface on the opposite side of where line 334 is printed and the lower surface is the surface in which the line is printed. Figure 4 shows a printed limit line 334 and is seen in column 26, line 35-43 which states, "The first opposable component 302 further includes a printed limit line 334 and a second conductor (Ahlstrom 1281) 336. The limit line 334 is located between the detection zone 332 and the second conductor 336. The first and second chromatographic medium 322 and 328 and the first and second conductors 326 and 336 are backed by a polycarbonate test strip backing (Lexan) 338.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAM P. SIEFKE whose telephone number is (571)272-1262. The examiner can normally be reached on M-F 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/
Primary Examiner, Art Unit 1797